



Whitening Lase II

User Manual

CE
0843

Whitening Lase II is a device manufactured with the highest technology and all the devices are tested individually. The device has the registration at the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária), assuring this way the fulfillment of the national regulations. This device also fulfills the requirements established by the European Community, being able to be commercialized in the European market.

Whitening Lase II was developed to be used by professionals of the oral and maxillofacial area. The surgeon must be qualified to the application of the equipment's related techniques. The inadequate usage may cause irreversible damages.



The manufacturer recommends all manual reading before using the product.

DEVICE FUNCTIONS

The Whitening Lase II device presents the following functions:

- Emits red (660 nm) and infrared (808 nm) laser light, with maximum power of 100mW for laser therapy;
- Emits infrared laser light (with power of 100mW) and blue light for dental whitening.

DEVICE FUNCTIONING

The device has two handpieces, one for laser therapy and another for dental whitening.

The laser therapy handpiece has a red laser and an infrared laser. The red light (red laser) interacts with the soft tissues and the invisible light (infrared laser) with hard tissues. These have analgesic, anti-inflammatory and healing properties.

The whitening handpiece has infrared lasers and blue LEDs. The infrared lasers are used in the dental whitening in order to diminish the sensibility after the whitening and in order to activate the whitening gel (by heating). The blue LEDs have the function of activating the whitening gel thorough the interaction of the light/dye.

INDICATIONS

The equipment use indications can be found below and in the equipment's assisted mode. For any different use, the manufacturer must be prior contacted.

LASER THERAPY

Soft Tissue Recovery

Ulcer and Traumatic Ulcer
Oral Manifestation of Systemic Diseases
Lichen Planus
Cheilitis Angular
Gingivitis
Postoperative
ATM Dysfunction

Bone Tissue Recovery

Orthodontia
Implantodonty
Periodontitis

Extraction
Traumatic Injury
Biostimulation of bones

Dental Tissue Recovery

Dentine Hypersensitivity

Nerve Recovery

Neuralgias
Paresthesias
Paralysis
Pain Syndrome

Other Applications

Alveolitis
Edema
Xerostomia
Pericoronitis
Anesthesia
Geographic Tongue
Simple Herpes
Zoster Herpes
Post endodontic

DENTAL WHITENING PDT (PHOTODYNAMIC THERAPY)

SPECIFICATIONS

Infrared Laser	Characteristics
Wavelength	808 nm \pm 10 nm
Emitter useful power	100 mW \pm 20%
Pulse Duration (Pulsed Mode)	05 ms – 50 ms

Red Laser (Target Laser)	Characteristics
Wavelength	660 nm \pm 10 nm
Emitter useful power	0,5 mW - 2,5 mW

Red Laser	Characteristics
Wavelength	660 nm \pm 10 nm
Emitter useful power	100 mW \pm 20%
Pulse Duration (Pulsed Mode)	05 ms – 50 ms

Blue Led	Characteristics
Wavelength	450 nm \pm 10 nm
Emitter useful power	400 mW \pm 20%

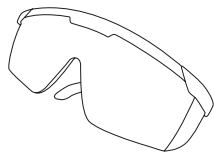
 The specified parameters are not subject to modifications due to time.

General Characteristics

Characteristics	Specifications
Voltage	90-240 V~
Power Input	50 VA
Operation Mode	Continuous
Frequency Power	50/60 Hz
Level of protection to the water and solid objects penetration	IP20
Operation Mode of the lasers	Continuous and pulsed operation
Applied Part	Laser therapy handpiece
Fuse	Nominal Current: 2 A
	Type: T
	Voltage: 250 V~
	Breaking Capacity: 35 A or L
Size	17 cm (depth) x 13 cm (width) x 15 cm (height)
Weight	1,28 Kg
Fiber Diameter	600 μ m
Type of Current	Alternating Current
Manufactured and tested according to:	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4 and IEC 60685-1.
Software version	8.10

SAFETY - IMPORTANT CAUTION

- ⚠ If any component present damage, it must not be used.
- ⚠ Considering that the product is used by a qualified surgeon, specific additional training is not necessary for the operation of the equipment, apart from the reading and understanding of the instructions manual.
- ⚠ The use of any part, accessory or material not specified it is the user's entire responsibility.
- ⚠ The laser light is harmful to the eyes, so the goggles must be used in order to protect them, for everybody in the place, where the session is happening. The DMC provides three goggles along with the Whitening Lase II. Only the goggles provided by the DMC may be used along with the device. The model of the before mentioned goggle can be seen below:



Goggles
(Green lenses)

- ⚠ Never look directly to the laser light and more importantly do not direct the light to anybody, unless he/she is under treatment.
- ⚠ Reflexive surfaces may reflect the laser beam in the eyes direction.
- ⚠ Never radiate tumor processes directly, the laser can stimulate them.
- ⚠ Never radiate the infectious processes directly, the laser can stimulate them.
- ⚠ Never radiate an undiagnosed injury.
- ⚠ Do not make extra-oral applications in patients that take photosensitizing drugs, any high intensity light can interact with the drug and provide spots at the radiation place.
- ⚠ Do not radiate the beam over the belly of women under three months of pregnancy.
- ⚠ The usage of flammable or oxidizable anesthetic gases, such as the nitrous oxide (N_2O) and oxygen, must be avoided. Some materials, for example cotton, when saturated with oxygen, may inflame by the high temperatures produced. The adhesive solvents and flammable solutions used for cleaning and disinfection must evaporate before the device is used.

- ⚠ Only trained people can operate the device. The inadequate usage can cause irreversible damages.
- ⚠ Only the components mentioned in this manual can be used together with the device.
- ⚠ In case of ceasing the emission of the laser quickly, the "red" button (STOP) (front panel) must be used.
- ⚠ It is not allowed the usage of the device by unauthorized and not qualified people, aiming at avoiding the incorrect or inappropriate usage. When not used, Whitening Lase II must be turned off, because when restarting it the access will only be permitted with the provided password. The responsible professional must store this password in a way that not qualified and unauthorized people do not have access to it.
- ⚠ The device must not be used with wires and accessories that are not provided by DMC, because it can result in increase of the emissions or decrease of the immunity of the Device.
- ⚠ The Device must not be used too close of piled over other devices. If it is necessary, we recommend that the Device is observed in order to check the Normal operation in the setup in which it is going to be used.
- ⚠ It does not exist an age limit concerning to the usage of the laser therapy handpiece. However, for the dental whitening, the patient must be at least 18 years old.
- ⚠ In case of laser therapy, the laser can be applied under any tissue conditions. However, for dental whitening the patient must:
 - Be with a healthy gum, with no inflammation and with no tartar;
 - Treat the teeth sensibility, if have;
 - Check if he/she has caries or permeation in the restorations.
- ⚠ The device is not designated to be used in an environment full of oxygen.
- ⚠ In order to avoid the risk of electrical shock, this device must be connected to only one power supply with grounding for protection.
- ⚠ The user must not connect the Cable A/C plug in places that are difficult to access, because it can make the device disconnection difficult.
- ⚠ None modification in this device is allowed.
- ⚠ The user must not connect the Cable A/C plug in places that are difficult to access, because it can make the device disconnection difficult.

⚠ The manufacturer does not take any responsibility if the user uses a fuse and an A/C cable different from the ones specified in this manual.


⚠ The user must be exposed to the noise the device does during the maximum period of 8 hours a day.

⚠ The air inputs and outputs must not be obstructed.

⚠ Do not apply any protective film in the handpieces.

SECUTIRY ITEMS OF THE DEVICE

The device has some security items, which include:

- Sound signal emission while the laser is active;
- Red emergency button (front panel) designated to interrupt immediately the laser output;
- Security password, which will allow the use of the device only by the responsible person;
- Indication, in the display, that the laser on by the symbol — .

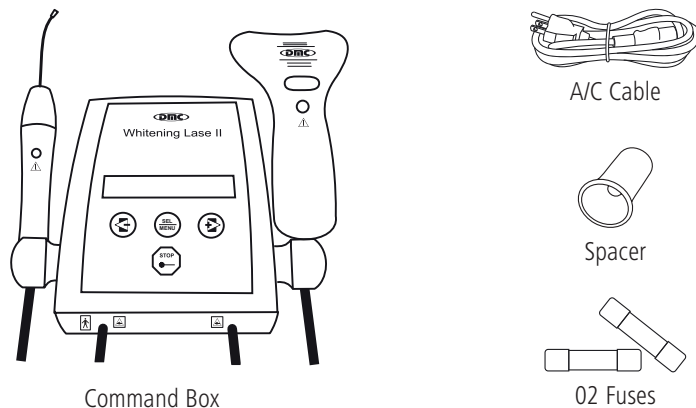
Target Beam

Whitening Lase II uses a target beam of low intensity. This visible laser is designated to indicate the application point.

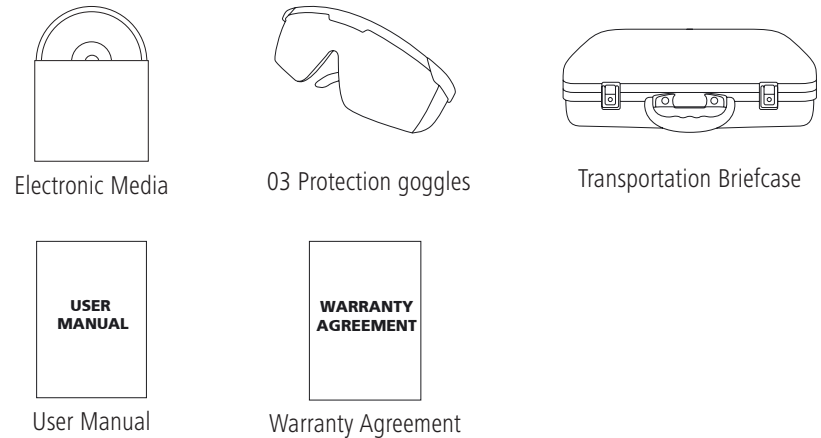
COMPONENTS LIST

Whitening Lase II is constituted by the following parts:

PARTS



ACCESSORIES

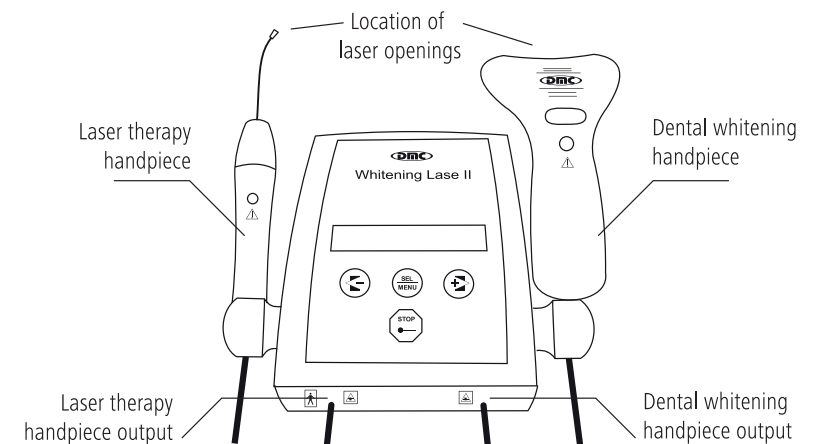


If the acquisition of any accessory is necessary, it must be bought at DMC Equipment through the following codes:

- A/C Cable: 010130037;
- Goggles: 050020001;
- Spacer: 110030078.

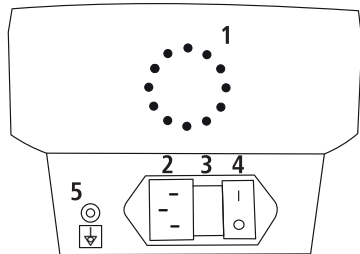
⚠ All the accessories and parts described above are for exclusive use in the Whitening Lase II device.

FRONT PANEL PARAMETERS



- Key : Increase the values and navigate through the available options
- Key : Decrease the values and navigate through the options available
- Key : Confirm/select parameters and functions.
- Key : Responsible for the immediate interruption of the laser, when necessary.

BACK PANEL PARAMETERS

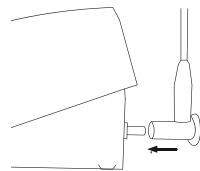


- (1) **Microfan:** Air exit place - must not be obstructed;
- (2) **Cable A/C connector:** Place where the cable A/C must be connected;
- (3) **Fuseholder:** Place where the device fuses are inserted;
- (4) **On/Off Switch:** Turns on and off the command box;
- (5) **Potential equalizer:** This connector establishes an equipotential connection. It is recommended that the grounding connection is done by qualified personnel.

Equalizer Function: The potential equalizer function is to equalize the power between the different metallic parts that can be touched simultaneously or reduce the power difference that may occur during the operation between the electromedical equipment housing and the conductive parts of other objects.

Kind of connector and cable: Use the cable with the connector related to the code POAG- K4FS/ KBT6DIN/100 (Manufacturer: Multi-Contact).

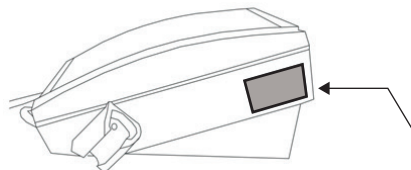
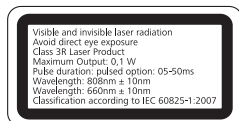
How to Connect: The connector before mentioned must be assembled in the potential equalizer, according to the picture beside:



LASER WARNINGS

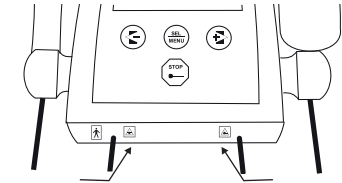
Side Panel Warnings

The label below indicates the laser radiation exposure.

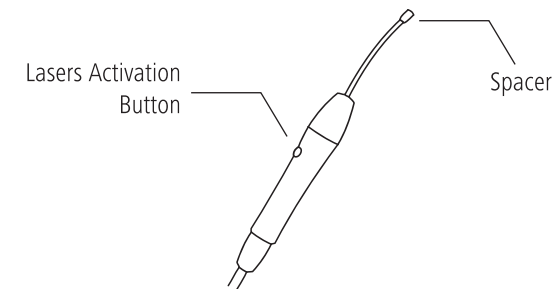


Front panel warnings

The label below illustrates the laser radiation warning.



LASER THERAPY HANDPIECE

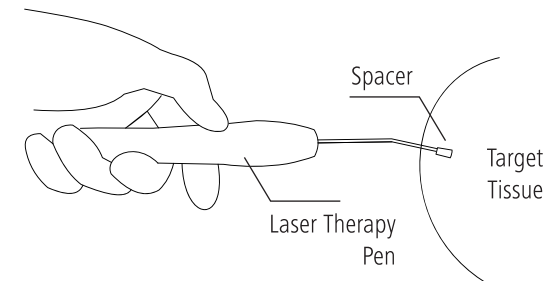


This handpiece has two lasers, one red and one infrared and must always be used when the laser therapy applications are performed. When this one is not being used it is important to keep it in its holder in order to not damage the optic fiber tip.

Spacer

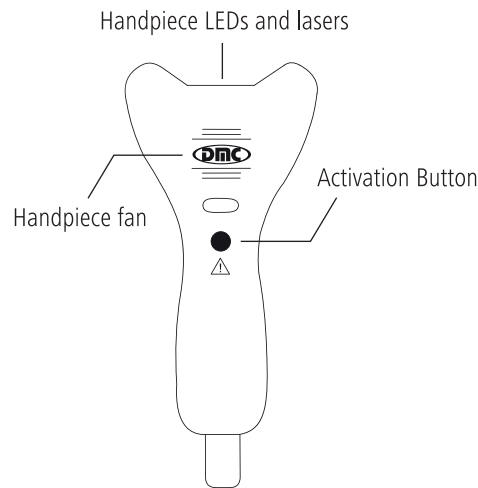


The spacer must be in contact with the target tissue in the moment of the application, according to what can be seen below.



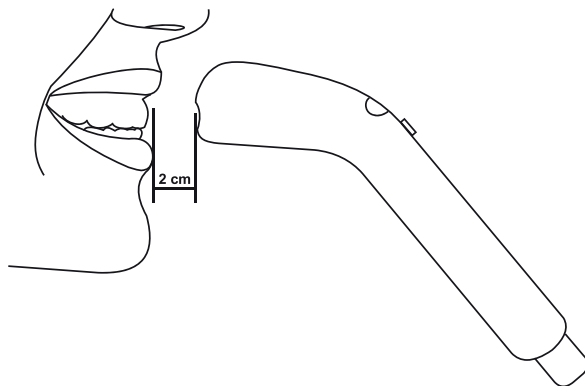
⚠ The spacer must be disinfected before using with alcohol 70%. However, after use it must be disposed. In order to acquire extra spacers contact DMC Equipment.

DENTAL WHITENING HANDPIECE



This handpiece has three infrared lasers and six blue LEDs and it must be used in the dental whitening. When it is not being used it is important to keep it in its holder in order to not get damaged.

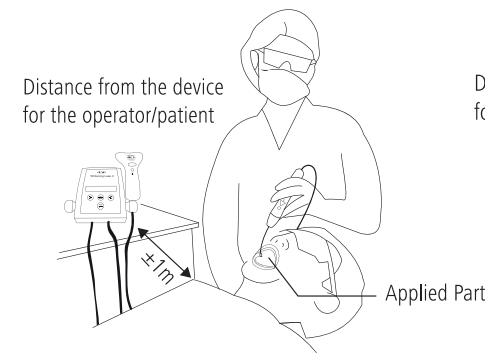
How to apply the handpiece can be seen below.



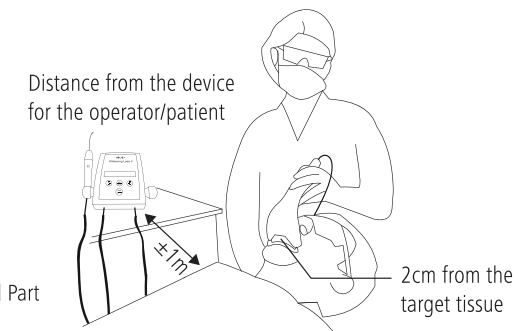
PATIENT / OPERATOR POSITION

The equipment shall be used in dental clinics. It should be placed on a worktop and connected to a power supply network. The hand pieces shall be positioned according to items "Dental Whitening Handpiece" and "Lasertherapy Handpiece". You can find images of the positions for the patient and the operator of the Whitening Lase II equipment below.

Lasertherapy function



Dental Whitening Function



DISINFECTION

Command box

- The device must be disconnected from the power supply before cleaning, in order to avoid the user exposition to electrical shock;
 - The command box must not be washed, it will imply in warranty loss;
 - The cleaning consists of using a soft cloth moistened with alcohol 70%.
- ⚠ Do not allow liquids to drain into the command box, because it will damage it.
- ⚠ The device can be cleaned/disinfected multiple times, with no damage.

Other items

All the other Items used with the device must be cleaned with alcohol 70%.

INSTALL





- Connect the A/C cable in the back part of the device;
- Then, insert the A/C cable in the power supply. The potential equalizer must be connected to the potential equalization bus of the power supply.




BEFORE USAGE INSPECTION

Check if all the items mentioned in the INSTALL are connected.

HOW TO USE

As you activate the on/off switch, located in the back panel, screens will be presented with some information like: Device's name, version, serial number, usage time and language selection option.




In order to select the language press , and then  or  to alternate between the options available, use the key  to confirm.

The usage of the equipment is restrict to the user through a password. By using the keys  or , insert the password provided in the warranty agreement, to allow the device to complete its initialization. Use the key  to validate the choice of each number of the password, got to the next digit and conclude, after the insertion of the forth digit.

After the password confirmation, the device accesses the "Main Menu", with the options "Setup Menu" and "Operation Screen".

SETUP MENU

In this screen it is possible to select the laser therapy and dental whitening modes. In the laser therapy it contains the options of the normal, assisted and PDT mode.

In order to navigate between the options, the keys  or  must be used and the key  to confirm.

LASER THERAPY

PDT




In this therapy, the device is set to act with the red laser, in the power of 100 mW during 1 minute and 30 seconds.




Application

In order to activate the laser, you just need to press the button of the laser therapy handpiece.




Normal Mode

In this item it is possible to select the wave length of the red laser (660 nm) or infrared (808 nm), to be used in the procedure. Use the navigation keys  or  and confirm with the key .




With the keys  or  will be possible to increase or decrease the power from 30 mW to 100mW in steps of 10 mW. By using the key  confirm the option chosen.

Having the power defined, the next screen will be the choice between CONTINUOUS or PULSED emission. The navigation between the options must be performed by the keys  or  and the confirmation by the key .

Pulse Adjustment

After choosing the pulsed mode in the previous item, it will be allowed to adjust the number of pulses per second to be used. With the keys  or  it is possible to vary between 10 pps and 100 pps (pulses per second). To confirm you must press the key .




Dosage Adjustment




Then, adjusting the dosage will be allowed, and it may vary from 10 J/cm² (minimum dosage) to 1000 J/cm² (maximum dosage). The adjustment must be performed by the keys  or  and the confirmation key is .

Application

In order to activate the laser, you just need to press the button of the laser therapy handpiece.

Opting for the Assisted Mode



With the keys  or  it will be possible to navigate between the preset therapies. As you have chosen the therapy, press the key .


Later, the display will show the minimum and the maximum dosage for the therapy. Inside this range, the professional may vary the value of the dosage by using the keys  or , confirming with the key .

Application

In order to activate the laser, you just need to press the button of the laser therapy handpiece.

DENTAL WHITENING

In this mode it is possible to select the application time, which may vary from 30 seconds to 3 minutes. In order to change the values the keys  or  must be used.

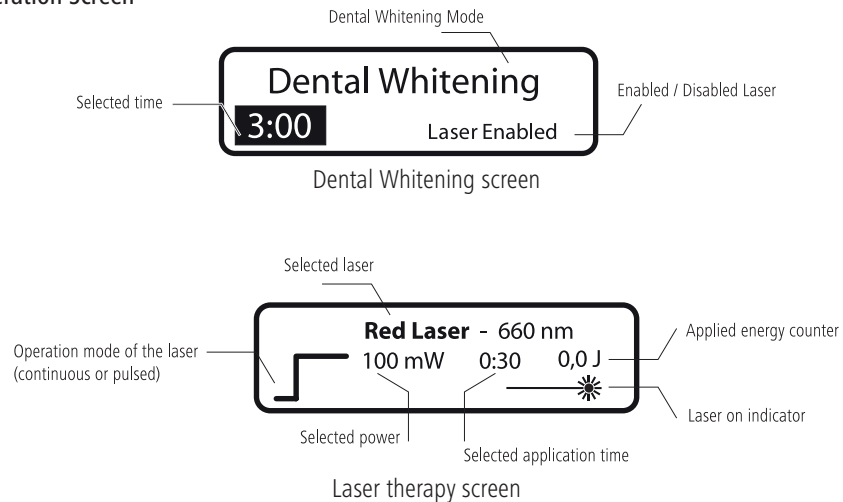
If the button  is pressed in the dental whitening working screen, will be available for the user the following options:

- Go back to the previous work screen;
- Enable or disable the laser in the dental whitening function;
- Restart the application time;
- Quit the dental whitening mode, back to the main menu

Application

In order to activate the dental whitening handpiece, just press its button.

Operation Screen



Important observations

- ⚠ During the product usage, the device will illustrate the time in a regressive way on the display.
- ⚠ If the user wants to go back to the main menu, being on the operation screen, he/she must press the button . At this moment, the following messages will be available: Back (returns to the previous screen), Restart time (restarts the time of the previous application screen) and Main Menu (return to the Adjust Menu/ Operation Screen). The choice of the option must be performed by the buttons or and the confirmation by the key .
- ⚠ If the user wants to interrupt the laser emission and LEDs at any moment of the application, only press the button in the handpiece.
- ⚠ The device has a display with user friendly menu. Warning messages can be shown at it.
- ⚠ As the infrared laser emitter is not visible, the device has a target light beam.
- ⚠ Attention - Control usage, or adjusts or execution of other procedures not specified here may result in harmful radiation.

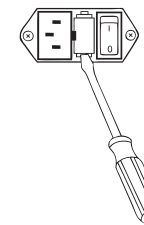
FINALIZATION PROCEDURE

In order to turn off the device, the user must use the On/Off switch located at the back panel.

SUPPLY ISOLATION

In case of emergency or for maintenance purposes, the supply plug (A/C Cable) must be disconnected from the electrical power supply, by removing it from the plug.

FUSE VERIFICATION AND CHANGE PROCEDURE



- Disconnect the A/C cable from the electrical power supply and from the device;
- By using a screwdriver, undock both edges of the fuse holder lid (see picture beside), until it is possible to remove it with the hands;
- Remove each one of the fuses and check if they are burnt – observe if the fuse is dark or with the thread broken;
- if necessary, replace the fuse using a spare fuse provided or another from the same value and features (see the item "SPECIFICATIONS");
- Push the fuse holder with the hands until it locks.

PREVENTIVE MAINTENANCE

The device must be calibrated at least every two years by the manufacturer. If this maintenance is not performed, the manufacturer does not take any responsibility for its safety.

All the assistance services, such as changes, repairs, calibration, etc. can only be performed by the manufacturer. The circuit schemas, components lists, descriptions, instructions for calibration and measurement are not available for people who are not qualified by the manufacturer.

If the maintenance or any other kind of assistance service is performed by unauthorized personnel, the manufacturer does not take any responsibility for the safety of the device functioning.

In order to assure the safe usage of the product, the user must inspect the integrity of the A/C cable, console and the handpieces in a daily basis, that is, check if these parts are not broken, torn, dirty, etc.

⚠ Never open the command box. At any problem contact the technical assistance of the DMC Equipment.

STORAGE AND TRANSPORTATION

- Store the device away from dust, solar direct exposure, near chemical products and cleaning agents;
- The device must be stored, transported and used in the following environmental conditions:
- Temperature: from +10°C to +40°C;
- Humidity: from 30% to 75%;
- Atmospheric Pressure: from 700hPa to 1060hPa.

⚠ Avoid the device falling.

⚠ Keep the device in a safe place, avoiding hits and vibrations.

PROBLEMS AND POSSIBLE SOLUTIONS

Error code	Type of error	Possible solutions
Error01	Locked Microfan	- Check for obstruction in the microfan; - Restart the device;- Contact the Manufacturer
Error02	High internal temperature error	- Clear air exits of the device.-Check the dental whitening handpiece microfan functioning and of the command box; - Contact the Manufacturer
Error03	Current in the emitter error (current above the specified)	- Restart the device; - Contact the Manufacturer
Error04	Current in the emitter drivers error	
Error05	Current in the emitter error (current below the specified)	
Error06	Error in the calibration reading of the emitters	
Error07	Error in the reading of the temperature sensors	
Error08	Memory reading failure	
Error09	Memory writing failure	
ER-A	The device do not turn of	- Check if the A/C Cable well connected; - Check, with the A/C cable disconnected from the power supply, if the fuse is burnt, according to the item "FUSE VERIFICATION AND CHANGE PROCEDURE"; - Check if the plug is working correctly.

DISCARDING

After the product and its accessories life has expired, it can cause environmental harm or can be used incorrectly. In order to minimize these risks, the client must discard the device according to what the local legislation determines.

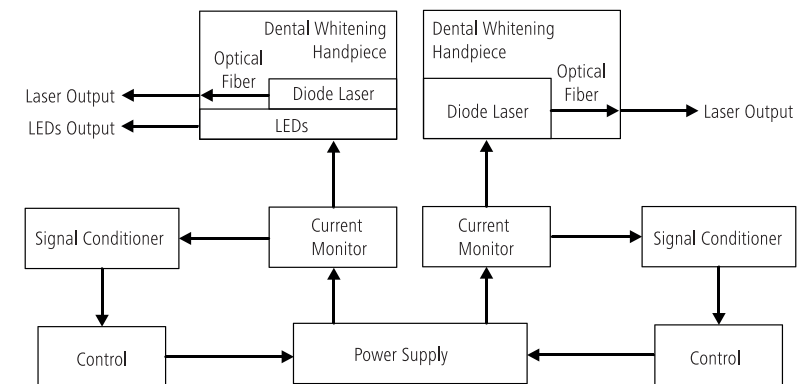
BIOCOMPATIBILITY

The part applied, that touches the patient, is in accordance with the requirements of the ISO 10993-1.

LASER SUPPLY SYSTEM

The laser therapy handpiece is composed by two diode lasers. The light is conduced to the edge of the handpiece by optical fiber, not replaceable. The optical power emitted is controlled through electrical current that passes by the diodes.

The dental whitening handpiece is composed by three infrared diode lasers and six blue LEDs. For the lasers the light is conduced to the edge of the handpiece by optical fiber, not replaceable. The blue light is transmitted directly through the LEDs. The optical power emitted is controlled through the electrical current that passes through the diodes and through the LEDs.



CALCULATION OF BEAM DIVERGENCE

Standard: IEC 60825-1:2007

The beam divergence is $0,45 \text{ rad} \pm 0,03 \text{ rad}$.

ELECTROMAGNETIC SAFETY STANDARD OF THE DEVICE

Below there are tables that represent the adjustment to the regulation of electromagnetic immunity and emission.

Guidelines and Manufacturer Statement - Electromagnetic Emission - For all the Device and System [IEC 60601-1-2 / 2007 – subcl. 6.8.3.201 a) 3)]		
The Whitening Lase II is designated for the usage in electromagnetic environment specified below. The client or user of the Whitening Lase II must assure that he/she is using it in such environment.		
Immunity Trial	Accordance	Electromagnetic Environment - Guideline
RF Emissions ABNT NBR IEC CISPR 11	Group 1 According	Whitening Lase II uses RF energy only for its internal functions. Thus, its RF emissions are very low which is not likely that cause any interference in the electronic devices nearby.
RF Emissions ABNT NBR CISPR 11	Class "A"	Whitening Lase II is convenient for using in all the places that are not designated to domestic use or that are not directly connected to a public power supply of low voltage that powers buildings used for the domestic matter.
Harmonic Emissions 61000-3-2	Not applicable	
Emissions due to voltage floating/scintillation IEC 61000-3-3	Not applicable	

Table 1: Accordance information to the electromagnetic emission requirements based in the table 201 – 60601-1-2, 2007

Guidelines and Manufacturer Statement - Electromagnetic Immunity - For All Whitening Lase II [IEC 60601-1-2 / 2007 – subcl. 6.8.3.201 a) 6)]			
The Whitening Lase II is designated for the usage in electromagnetic environment specified below. The client or user of the Whitening Lase II must assure that he/she is using it in such environment.			
Immunity Trial	Level of the ABNT NBR IEC60601 trial	Level of Accordance	Electromagnetic environment - Guideline
Electrostatics discharge (ESD) IEC 61000-4-2	± 6 kV per contact ± 8 kV through the air	According	Floors must be made of wood, concrete or ceramic. If the floors are covered with synthetic material, the relative humidity must be at least 30%.
Fast electric transitory/ pulse train ("Burst") IEC 61000-4-4	± 2 kV in the power lines ± 1 kV in the input/output lines	According	Quality of the energy must be the one from a hospital environment or typical commerce.
Outbreaks IEC 61000-4-5	± 2 kV line (s) to ground ± 1 kV line (s) to line	According	Quality of the energy must be the one from a hospital environment or typical commerce.
Voltage drops, short interruptions and voltage variations in the input supply line IEC 61000-4-11	<5% Ut (>95% of voltage drop in Ut) per 0,5 cycles. 40% Ut (60% of voltage drops in Ut) per 5 cycles 70% Ut (30% Of voltage drops in Ut) per 25 cycles. <5% Ut (>95% of voltage drops in Ut) per 5 seconds	According	Quality of the energy must be the one from a hospital environment or typical commerce. If the user of the Whitening Lase II demands continuous operation during the energy interruption, It is recommended that the Whitening Lase II is supplied by a uninterruptable power supply or a battery.
Magnetic field in the supply frequency (50/60Hz) IEC 61000-4-8	3 A/m	According	Magnetic fields in the supply frequency must be in specific levels of a typical place in a hospital environment or typical commerce.
NOTE: Ut is the supply voltage c. a. before the application of the trial level.			

Table 2: Accordance Information to the electromagnetic immunity requirements based on the table 202 – 60601-1-2, 2007


Guidelines and manufacturer statement - Electromagnetic Immunity - Device that is not from LIFE SUPPORT - [IEC 60601-1-2 / 2007 – subcl. 6.8]			
The Whitening Lase II is designated for the usage in electromagnetic environment specified below. The client or user of the Whitening Lase II must assure that he/she is using it in such environment.			
Immunity Trial	Level of the IEC 60601	Level of accordance	Electromagnetic Environment - Guideline
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz up to 80 MHz	3 V	Portable and mobile RF communication devices should not be used nearby any part of the Whitening Lase II, including cables, with separation shorter than the recommended, calculates from the equation applicable to the transmitter frequency. Separation distance recommended D = 10,10 m D = 10,10 m (80 MHz up to 800 MHz) D = 20,20 m (800 MHz up to 2,5 GHz) Where P is the maximum output nominal power of the transmitter in watts (W), according to the manufacturer of the transmitter, and D is the recommended separation distance in meters (m). It is recommended that the intensity of the field established by the RF transmitter, as determined by an electromagnetic inspection at the local ^a , is smaller than the accordance level in each frequency range ^b . Interference may happen around the device marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz up to 2,5 GHz	3 V/m	
<p>NOTE 1 - In 80 MHz and 800 MHz, applies to the higher frequency range</p> <p>NOTE 2 - These guidelines cannot be applied in all the situations. The electromagnetic propagation is affected by the structure absorption and reflection, objects and people.</p> <p>^a The intensities of the field established by the fixed transmitters, such as radio stations base, telephone (cell Phone/ wireless) and mobile terrestrial radios, amateur radio, radio transmission AM and FM and TV transmitters do cannot be accurately foreseen theoretically. In order to evaluate the electromagnetic environment due to the fixed RF transmitters, it is recommended an electromagnetic inspection at the local. If the measurement of the field intensity at the local in which Whitening Lase II is used exceeds the accordance level used above, the Whitening Lase II should be observed to check if the operation is normal. If an abnormal development is observed, additional procedures may be necessary, such as a reorienting or rearranging of the Whitening Lase II</p> <p>^b Over the frequency range of 150 kHz up to 80 MHz, the field intensity should be lower than 3 V/m</p>			

Table 3: Accordance information to the electromagnetic immunity requirements for devices which aims at LIFE-SUPPORT based on the Table 204 – 60601-1-2, 2007

Distance and minimum separation recommended between the RF portable and mobile communication devices and the Whitening Lase II			
The Whitening Lase II is designated for using at the electromagnetic environment in which radiated RF disturbances are controlled. The client or user of Whitening Lase II may help to prevent the electromagnetic interference keeping the minimum distance between the portable or mobile RF communication (transmitters) and the Whitening Lase II, as recommended below, according to the maximum output power of the communication devices.			
Nominal maximum power of the transmitter (W)	Separation distance according to the transmitter frequency (m)		
	150 kHz up to 80 MHz	80 MHz up to 800MHz	800 MHz up to 2,5 GHz
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,2	1,2	2,3
10	3,7	3,7	7,4
100	12	12	23
For transmitters with an output nominal maximum power not listed above, the separation distance recommended (in meters [m]) can be determined by the equation applicable for the transmitter frequency.			
<p>Note 1: In 80 MHz up to 800 MHz, the separation distance is applied for the highest frequency range.</p> <p>Note 2: These guidelines cannot be applied in all situations. The electromagnetic propagations are affected by the structure absorption and reflection, objects and people.</p>			

Table 4: separation distance between the device and the RF emission sources recommendations based on the Table 206 – 60601-1-2, 2007

SYMBOLS USED



Laser Radiation



Terminal of power equalization



Applied part type B



Check the user's manual



Caution



Protected against solid strange objects of 12,5 mm of diameter and not protected against water drain.



On (with voltage)



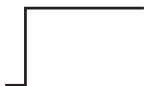
Off (without Voltage)



Date of Manufacture



Manufacturer



Continuous operation. The laser device is selected for a mode where the exposure duration is limited by the chosen dosage, counting that the activation button is pressed.



Repetitive Exposure. The laser device is selected for a mode where a series of exposures is available with certain duration and a certain frequency, counting that the activation button is pressed.



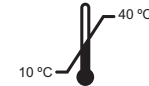
Alternate Current



Serial Number



Turn off the laser because of an emergency



Temperature limits



Humidity Limitation



Authorized Representative in the European Community



Fragile, handle with care



Indicates the position for transport



Keep away from sunlight



Protect from heat and radioactive sources



Keep dry



Do not overturn



Maximum Pilling

WARRANTY

- A.** The devices manufactured and/or commercialized by DMC have a 24 (twenty-four) months warranty, from the date of the purchase, against any manufacturing defect.
- B.** The warranty covers only manufacturing defects or of material used in the manufacturing of the products. The warranty DO NOT covers shipping expenses.
- C.** The warranty is automatically cancelled, in case of any electrical or physical abuse happen, if the parts were altered, or if applications different from those the device is developed for happened.
- D.** In case of repaired devices out of the warranty period, it will only be extended to the replaced parts.
- E.** The causes of the defects more common come from physical shock applied to the device, in these cases the warranty is cancelled.
- F.** The DMC does not take any responsibility for personal or material damages from the misuse of the devices they manufacture and/or commercialize, it is the user's responsibility to provide safety procedures in order to avoid such problems.
- G.** The DMC responsibility concerning to the use of the device and its consequences, limits to the replacement of the amount of the device.
- The device will only be under the manufacturer warranty regulations if:
- The assembling, extensions, adjusts, modification or repair operations were performed by people authorized by them;
 - the electrical installation of the environment in focus is in accordance with the appropriate requirement;
 - The device is used according to the instructions.



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Tec. Resp. Renaldo Massini Jr. – CREA 0601706815
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